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CVS settles meth case for $75M

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LOS ANGELES -- CVS Pharmacy Inc. has agreed to pay $75 million in fines for allowing repeated purchases of a key ingredient in the making of methamphetamine in at least five states that also led to a spike in Southern California drug trafficking, authorities said Thursday.

The nation's largest operator of retail pharmacies will pay what federal prosecutors said was the largest civil penalty ever assessed under the Controlled Substances Act.

The company also will forfeit about $2.6 million in profits earned from the sales of pseudoephedrine, which can often be found in cold medicine and is used to make meth.

Authorities said CVS didn't provide enough safeguards to monitor how much pseudoephedrine someone was buying, and the company violated federal drug regulations in Arizona, Georgia, California, Nevada, South Carolina and possibly 20 other states.

"CVS knew it had a duty to prevent methamphetamine trafficking," said U.S. Attorney Andre Birotte Jr. "But it failed to take steps to control the sale of a regulated drug used by methamphetamine cooks as an essential ingredient for their poisonous stew."

The company was expected to pay the $75 million fine by Friday. The remaining forfeiture is due within 30 days.

Thomas Ryan, chairman and CEO of parent company CVS Caremark, said the company unacceptably breached its policies and has worked to fix the problem.

"To make certain this kind of lapse never takes place again, we have strengthened our internal controls and compliance measures and made substantial investments to improve our handling and monitoring of (pseudoephedrine) by implementing enhanced technology and making other improvements in our stores and distribution centers," Ryan said.

Federal agents began investigating CVS in 2008 after the arrest of several people in Southern California for unlawful possession of pseudoephedrine with the intent to manufacture meth. They said those people had bought large amounts of the ingredient from CVS stores in the region.

Investigators learned CVS had committed thousands of violations of a federal law limiting the amount of pseudoephedrine a customer can buy in a day. Although the pharmacy chain created an automated system known as Meth Tracker to record individual sales, it didn't prevent multiple purchases by someone on the same day, authorities said.

As a result, federal authorities in Southern California saw an increase in meth production. In Los Angeles and Orange counties, so-called "smurfers," who traveled from store to store picking up pseudoephedrine, inundated CVS locations. In some locations, buyers would clear store shelves of cough and cold medicines.

Between September 2007 and November 2008, CVS became one of the largest suppliers of pseudoephedrine to meth providers in Southern California, authorities said.

"CVS did not set out to be part of the meth trafficking trade but they made a poor decision," said Assistant U.S. Attorney Shana Mintz. "Rather than choosing to over-comply like their competitors did, they knowingly under-complied with the law."

CVS employees and store managers notified management about the large amount of pseudoephedrine purchased in California and Nevada, but prosecutors said the company failed to promptly investigate.

CVS spokeswoman Carolyn Castel declined comment on that issue.

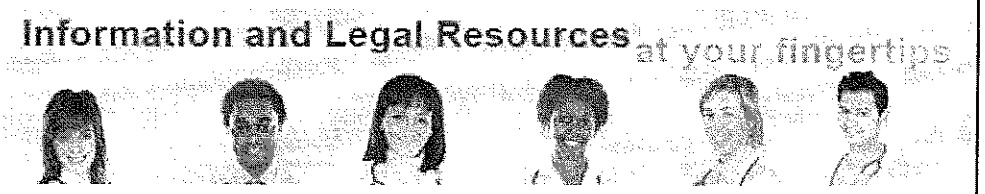
Over a 10-month period in 2008, sales of products containing pseudoephedrine increased more than 150 percent in Los Angeles County, compared with the same period in 2007, authorities said.

"We know those sales were not your general customer who had a cold," Mintz said. "Some people were making 10 purchases at a time. Suppliers couldn't keep up with the demand."

The company eventually changed its sales practices but only after it became aware of the investigation, prosecutors said.

By agreeing to pay the fine, CVS will not face potential criminal charges and the company will implement a compliance and ethics program over the next three years.

CVS has more than 7,100 stores in the U.S.



Combat Methamphetamine Epidemic Act 2005 (Title VII of Public Law 109-177)

General Information Regarding The Combat Methamphetamine Epidemic Act of 2005 [Title VII of Public Law 109-177]

Drug Enforcement Administration
May 2006

The Combat Methamphetamine Epidemic Act of 2005 (**Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177**) was signed into law March 9, 2006. All changes go into effect on March 9, 2006, (date the legislation was signed) unless a later effective date is specifically stated. This document discusses those changes made by the Combat Methamphetamine Epidemic Act which primarily affect persons selling products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Other actions taken by the Combat Methamphetamine Epidemic Act are not discussed here.

Effective March 9, 2006

The Act makes definitional changes to add "scheduled listed chemical product," "regulated seller," "mobile retail vendor," "at retail," and to modify the existing definition of "retail distributor." Definitions are as follows:

"The term *scheduled listed chemical product* means,...a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical."

"The term *regulated seller* means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor."

"The term *mobile retail vendor* means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes)."

"The term *at retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively."

"The term *retail distributor* means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales."

Effective April 8, 2006

a. The change to **21 U.S.C. § 830** that adds a new subsection (d) SCHEDULED LISTED CHEMICALS; RESTRICTIONS ON SALES QUANTITY; REQUIREMENTS REGARDING NONLIQUID FORMS:

i. This sets the daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base at 3.6 grams per purchaser, regardless of the number of transactions.

ii. Affects regulated sellers and persons required to submit mail order reports under 21 U.S.C. 830(b)(3).

iii. Requires all nonliquid forms (including gel caps) to be in 2-unit blister packs (with exception when blister pack is not technically feasible, the product may be in unit dosage packets or pouches).

b. The change to 21 U.S.C. § 830 that adds (2) MAIL-ORDER REPORTING; VERIFICATION OF IDENTITY OF PURCHASER; 30-DAY RESTRICTION ON QUANTITIES FOR INDIVIDUAL PURCHASES:

i. This requires the mail-order seller to confirm the identity of the purchaser prior to shipping the product.

ii. Limits such sales to 7.5 grams per customer during a 30-day period.

c. The change to **21 U.S.C. § 844(a)** entitled RESTRICTIONS ON QUANTITY PURCHASED DURING 30-DAY PERIOD:

i. This makes it unlawful for any person to knowingly or intentionally purchase at retail more than 9 grams during a 30 day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).

Effective September 30, 2006

Sales limits

a. A mobile retail vendor may not sell more than 7.5 grams of product per customer during a 30-day period.

Product Placement

b. Regulated seller must place product such that customers do not have direct access before the sale is made ("behind the counter" placement) or in a locked cabinet that is located in an area of the facility to which customers do have direct access. Regulated seller must deliver product directly into the custody of the purchaser.

c. A mobile retail vendor must place product in a locked cabinet.

Logbook Provisions

d. Seller maintains written or electronic list (logbook) of sales that identifies:

(1) Products by name;

(2) Quantity sold;

(3) Names and addresses of purchasers; and,

(4) Date and time of the sales.

The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 mg. of pseudoephedrine.

e. Seller may not sell the product unless prospective purchaser presents a photographic identification card issued by a State or the Federal Government, or a document considered acceptable for purposes of 8 CFR § 274a.2(b)(1)(v)(A) or (B).

f. Purchaser must sign the logbook and enter his or her name, address, and date and time of sale.

g. Seller must determine that the name entered into the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

h. Seller must enter into the logbook the name of the product and the quantity sold.

i. The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. § 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

j. Seller must maintain each entry in the logbook for not fewer than two years after the date on which the entry is made.

k. The Attorney General will issue regulations establishing restrictions on disclosure of information in logbooks. Disclosure to the Attorney General and to State and local law enforcement agencies will be authorized. Accessing, using, or sharing the logbook information for any purpose other than to comply with the Controlled Substances Act or to facilitate a product recall to protect public health and safety will be prohibited.

"(aa) determines that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct; and

"(bb) enters in the logbook the name of the product and the quantity sold.

"(v) The logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchasers to criminal penalties under section 1001 of title 18, United States Code, which notice specifies the maximum fine and term of imprisonment under such section. Notification.

"(vi) The seller maintains each entry in the logbook for not fewer than two years after the date on which the entry is made.

"(vii) In the case of individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d).

"(viii) The seller maintains a copy of such certification and records demonstrating that individuals referred to in clause (vii) have undergone the training.

"(ix) If the seller is a mobile retail vendor:

"(I) The seller complies with clause (i) by placing the product in a locked cabinet.

"(II) The seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

"(B) ADDITIONAL PROVISIONS REGARDING CERTIFICATIONS AND TRAINING.—

"(i) IN GENERAL.—A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in such subparagraph, the certification includes a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements.

"(ii) ISSUANCE OF CRITERIA; SELF-CERTIFICATION.—The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall—

"(I) provide that the certifications are self-certifications provided through the program under clause (iii);

l. Regulated seller who in good faith releases logbook information to Federal, State or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

Self-Certification and Training

m. Self-certification and training.

(1) Seller must self-certify to the Attorney General that each individual who is responsible for delivering such products into the custody of purchasers, or who deals directly with purchasers by obtaining payment for the products, has undergone training provided by the seller to ensure that the individual understands the requirements that apply to the sale of these products.

(2) Regulated seller may not sell any scheduled listed chemical product at retail unless the self-certification has been submitted to the Attorney General.

(3) Seller must maintain a copy of such self-certification and records demonstrating that individuals have undergone such training.

(4) The certification is not effective unless, in addition to provisions regarding the training of individuals, the certification includes a statement that the seller understands each of the requirements regarding transactional limits, blister-packs, "behind the counter" placement, photo identification, and logbook also apply and agrees to comply with the requirements.

(5) The Attorney General will issue regulations to establish the criteria for self-certifications and employee training. Separate certification is required for each place of business at which a regulated seller sells such products at retail.

(6) The Attorney General will establish a program that will:

(a) be carried out through an Internet site of the Department of Justice;

(b) inform regulated sellers that 18 U.S.C. § 1001 applies to such certifications;

(c) make available to sellers the criteria for certification and training;

(d) be designed to permit submission of certifications through the Internet site; and

(e) be designed to automatically provide the explanation of the criteria for certification and training and an acknowledgment that the Department of Justice has received a certification, without requiring direct interaction of regulated sellers with staff of the Department of Justice.

(7) Copies of certifications shall be made available to appropriate State and local officials.

Equivalency Charts

The following is not found within DEA law or regulations; DEA provides this for informational purposes only:

A. Effective April 8, 2006, the daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base is 3.6 grams per purchaser, regardless of number of transactions.

Ingredient	Number of Tablets [as base]
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

Ingredient	Number of Milliliters (ml) [as base]
6.25 mg/5 ml Ephedrine HCl	3515
15 mg/1.6 ml Pseudoephedrine HCl	468

7.5 mg/5 ml Pseudoephedrine HCl	2929
15 mg/5 ml Pseudoephedrine HCl	1464
15 mg/2.5 ml Pseudoephedrine HCl	732
30 mg/5 ml Pseudoephedrine HCl	732
30 mg/2.5 ml Pseudoephedrine HCl	366
60 mg/5 ml Pseudoephedrine HCl	366
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

B. Effective April 8, 2006, for mail-order sellers, sales are limited to 7.5 grams per customer during a 30-day period.

Ingredient	Number of tablets [as base]
25 mg Ephedrine HCl	366
25 mg Ephedrine Sulfate	389
30 mg Pseudoephedrine HCl	305
60 mg Pseudoephedrine HCl	152
120 mg Pseudoephedrine HCl	76
30 mg Pseudoephedrine Sulfate	324
60 mg Pseudoephedrine Sulfate	162
120 mg Pseudoephedrine Sulfate	81
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

Ingredient	Number of Milliliters (ml) [as base]
6.25 mg/5 ml Ephedrine HCl	7323
15 mg/1.6 ml Pseudoephedrine HCl	976
7.5 mg/5 ml Pseudoephedrine HCl	6103
15 mg/5 ml Pseudoephedrine HCl	3051
15 mg/2.5 ml Pseudoephedrine HCl	1525
30 mg/5 ml Pseudoephedrine HCl	1525
30 mg/2.5 ml Pseudoephedrine HCl	762
60 mg/5 ml Pseudoephedrine HCl	762
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

C. Effective April 8, 2006, it is unlawful for any person to knowingly or intentionally purchase at retail more than 9 grams during a 30-day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).

Ingredient	Number of tablets (7.5 gm) [as base]	Number of tablets (9 gm) [as base]
25 mg Ephedrine HCl	366	439
25 mg Ephedrine Sulfate	389	466
30 mg Pseudoephedrine HCl	305	366
60 mg Pseudoephedrine HCl	152	183
120 mg Pseudoephedrine HCl	76	91
30 mg Pseudoephedrine Sulfate	324	389
60 mg Pseudoephedrine Sulfate	162	194
120 mg Pseudoephedrine Sulfate	81	97
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.	

Ingredient	Number of milliliters (ml) (7.5 gm) [as base]	Number of milliliters (9 gm) [as base]